



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,630	01/25/2002	Ronald M. Burch	200.1079CON5	3300

7590 06/19/2006
Davidson, Davidson & Kappel, LLC
14th Floor
485 Seventh Avenue
New York, NY 10018

EXAMINER

GROSS, CHRISTOPHER M

ART UNIT	PAPER NUMBER
----------	--------------

1639

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/057,630		BURCH ET AL.	
	Examiner		Art Unit	
	Christopher M. Gross		1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38 and 47-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 38, 47-53 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 38 and 47-53 are pending. Claims 38 and 47-53 are under consideration.

Priority

This application is a CON of application 09/154354 (9/17/1998) which claims benefit of provisional application 60/059195 (9/18/1997) under 35 USC 119(e).

Maintained Claim Rejection 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 38, 47-48, 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,569,937 (Baker et al) and Swingle et al (Drugs Exptl. Clin. Res. Vol. X(8-9) (1984) pages 587-597) and/or Rabasseda. (Drugs of Today Vol. 32, No. 5 (1996) pages 365-384). This rejection maintains the reasons set forth in the previous Office action.

Response to Arguments

Applicant argues: (i) the transitional phrase "consisting essentially of" set forth in claim 38 is closed language; (ii) the Baker reference teaches away from the claimed invention.

Applicant's arguments have been considered but they are not persuasive.

In regard to "consisting essentially of" being closed language, according to MPEP 2113.03, absent a clear indication in the specification or claims of what the basic and

Art Unit: 1639

novel characteristics actually are, the phrase "consisting essentially of" will be construed as equivalent to "comprising."

Applicant argues, see p 4 (3/31/2006) that the claim excludes any analgesic compounds not recited and is limited to only the two recited compounds (nimesulide and oxycodone, or their respective salts). However, the claim does not explicitly state a limitation concerning only two active ingredients. Therefore applicant argues limitations not found in the claims.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Futhermore, it is noted that the abstract uses the phrase "a pharmaceutical composition, comprising a combination of a dose of nimesulide or a pharmaceutically acceptable salt thereof and a dose of oxycodone, or a pharmaceutically acceptable salt thereof."

Therefore, the transitional phrase "consisting essentially of" is construed as equivalent to comprising (open) due to lack of clarity in the claims and specification.

Applicant argues, see p 5-6 (3/31/2006), that the Baker et al reference would discourage one of skill in the art from using nimesulide with oxycodone, based on two quotations from Baker et al concerning the advantages of ibuprofen combined with narcotic analgesics. Applicant surmises that Baker et al teaches away from the claimed invention, namely combining the NSAID nimesulide with the narcotic oxycodone.

However, Applicant's attention is respectfully invited to column 1, lines 23-25, where Baker et al explicitly state "This patent discloses that the analgesic effect of the combination of a selected NSAID and a selected narcotic analgesic is greater than for either alone."

Thus, Baker et al teach that the entire genus of NSAIDs plus narcotic analgesics as providing beneficial analgesia. Ibuprofen represents a preferred embodiment for Baker et al and according to MPEP 2123 II, "disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments." Applicant cites case law (3/31/2006 p6) in that the Examiner cannot "pick an choose among the individual elements of assorted prior art references to recreate the claimed invention..." as found in SmithKline Diagnostics, Inc. v. Helena Laboratories Corporation, 859 F.2d 878, 887 (Fed. Cir. 1988). However, Applicant will respectfully note, said case citation continues, "...Helena [i.e. Examiner] has the burden to show some teaching or suggestion in the references to support their use in the particular claimed combination" The Examiner submits that aforementioned quotation of Baker et al provides a suggestion to use the combination of nimesulide with oxycodone.

Applicant argues, see p6 (3/31/2006) that the principle of operation would change when substituting the nimesulide of Swingle et al or Rabuseda for the NSAID in Baker et al.

However, both ibuprofen and nimesulide are anti-inflammatory compounds, specifically inhibitors directed against the enzyme COX2, involved in prostaglandin

Art Unit: 1639

synthesis, facts well recognized in the prior art. Thus both ibuprofen and nimesulide operate under the same principle. Therefore, the substitution of nimesulide for ibuprofen per Baker et al in view of Swingle et al or Rabasseda, rather than altering the principle of operation, represents substituting equivalents known for the same purpose, yet another basis for obviousness according to MPEP 2144.06.

As set forth *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), it is *prima facie* obvious to combine two [or more] compositions, each of which is taught by the prior art, in order to form a third composition to be used for the very same purpose (i.e. pain management or analgesia).

In summary, Baker et al does not teach away from the claimed invention. The instant claimed combination of nimesulide plus oxycodone would be obvious per Baker et al in view of Swingle or Rabasseda based on three criteria including combining equivalents known for the same purpose, substituting equivalents for the same purpose and one of skill in the art would have been motivated to use nimesulide due to its improved gastrointestinal tolerance (as covered in the last Office Action).

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (US patent 4,569,937), Swingle et al. and/or Rabasseda as applied to claims 38, 47-48, and 50-53 above, and further in view of Oshlack et al. US Pat. No. 5,472,712 (12/95) or Oshlack et al. US Pat. No. 6,294,195 (9/01: effectively filed 10/93 or earlier). This rejection maintains the reasons set forth in the previous Office action.

Applicant argues that the Oshlack references do not cure the deficiencies of Baker et al in view of Swingle et al or Rabasseda.

Applicant's arguments are insufficient to disregard Baker as a pertinent reference. The reference of Baker does not teach away from the claimed invention as described above.

Conclusion

Claims 38 and 47-53 stand finally rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PETER PARAS, JR.
PRIMARY EXAMINER



Christopher M Gross
Examiner
Art Unit 1639

cg